UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

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THE PORT AUTHORITY OF ALLEGHENY COUNTY RETIREMENT AND DISABILITY ALLOWANCE PLAN FOR EMPLOYEES REPRESENTED BY LOCAL 85 OF THE AMALGAMATED TRANSIT UNION,

Civil Action Control C

Plaintiff,

ECF Case

- against -

DENNIS A. AUSIELLO, MICHAEL S. BROWN, M. ANTHONY BURNS, ROBERT N. BURT, W. DON CORNWELL, WILLIAM H. GRAY III, CONSTANCE J. HORNER, JAMES M. KILTS, JEFFREY B. KINDLER, GEORGE A. LORCH, DANA G. MEAD, SUZANNE NORA JOHNSON, STEPHEN W. SANGER, WILLIAM C. STEERE, JR., DOUGLAS M. LANKLER, FRANK A. D'AMELIO, IAN C. READ, JOSEPH M. FECZKO, HENRY A. McKINNELL, DAVID L. SHEDLARZ, WILLIAM R. HOWELL, STANLEY O. IKENBERRY, FRANKLIN D. RAINES, RUTH J. SIMMONS, JEAN-PAUL VALLÈS, FREDA C. LEWIS-HALL, and PFIZER INC.,

VERIFIED COMPLAINT

Jury Trial Demanded

Defendants.

Plaintiff alleges, upon information and belief based upon, *inter alia*, the investigation made by and through her attorneys and experts, except as to those allegations that pertain to the plaintiff herself, which are alleged upon knowledge, as follows:

1. The jurisdiction of this Court is founded upon 15 U.S.C § 78aa and 28 U.S.C. §§ 1331, 1332, and 1367. The plaintiff is a citizen of the Commonwealth of Pennsylvania. The defendants are all citizens of states or commonwealths other than Pennsylvania. The matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

- 2. The claims herein arise under § 14(a) of the Securities Exchange Act of 1934 (the "Act"), 15 U.S.C. § 78n(a), Securities and Exchange Commission ("SEC") Rule 14a-9, 17 C.F.R. § 240.14a-9, and under the laws of the several states including, particularly, the State of Delaware and the State of New York. In addition, substantial questions arise under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the rules and regulations of the United States Food and Drug Administration ("FDA") and other federal statutes, rules, and regulations.
- 3. Plaintiff brings this action as a stockholder's derivative action in the right of and for the benefit of defendant Pfizer Inc. (the "Company" or "Pfizer"). This action is not a collusive one to confer jurisdiction that the court would otherwise lack.
- 4. Plaintiff brings this action to shift the burden from Pfizer of a \$2.3 billion settlement, announced on September 2, 2009, involving criminal and civil issues of the fraudulent marketing of drugs, the payment of bribes and kickbacks, and federal and state false claims, to Pfizer's board of directors, former directors, and senior management, who caused it. Pfizer booked this charge in the fourth quarter of 2008.
- 5. The \$2.3 billion settlement follows flagrant, recidivous conduct of both a criminal and civil nature, resulting in a vast multiple regulatory and enforcement actions well known to the Company's present and former directors and present and former senior executives. This is not the first train wreck caused by Pfizer's unfaithful and torpid management, against which, according to Delaware law, a stockholder's derivative action, such as this one, is a potent remedy.
- 6. In 2002, Pfizer was required to pay \$49 million to settle a case concerning illegal kickbacks for prescribing its anti-cholesterol drug Lipitor. In addition, Pfizer then entered into a

Corporate Integrity Agreement that required an internal compliance officer to make at least semiannual reports concerning its compliance directly to the Company's board of directors.

- 7. In 2004, Pfizer had to pay a \$240 million criminal fine and \$190 million for civil False Claims Act liabilities for promoting illegal use of its drug Neurontin. Then, Pfizer entered into another Corporate Integrity Agreement to prevent future violations. This Corporate Integrity Agreement again required Pfizer's internal compliance officer to make at least semi-annual reports directly to the Company's board of directors.
- 8. In 2007, Pfizer paid \$34.6 million in fines for the illegal promotion and sales practices of Genotropin.
- 9. As a result of these events, the Company's board of directors was acutely aware of the pervasive culture of white collar criminality at the highest levels of management. Yet, the senior management continued on its reckless course, for the board, resolvedly, took no action to stop them.
- 10. Plaintiff is a stockholder of the Company and was a stockholder at the time of the transactions complained of herein and has been such continuously since then. Plaintiff intends to continue to hold Pfizer shares at least through the resolution of this action. Plaintiff is a citizen of the Commonwealth of Pennsylvania.
- 11. Defendant Pfizer is a Delaware corporation with its principal place of business in the State of New York. Pfizer is a citizen of the State of Delaware and the State of New York.
- 12. Defendant Dennis A. Ausiello ("Ausiello") has been a director of the Company and a member of the board's corporate governance committee since 2006. Ausiello is a citizen of the Commonwealth of Massachusetts.

- 13. Defendant Michael S. Brown ("Brown") has been a director of the Company since 1996. In addition, Brown has been a member of the board's corporate governance committee. Brown is a citizen of the Great State of Texas.
- 14. Defendant M. Anthony Burns ("Burns") has been a director of the Company since 1998. Burns has been a member of the board's executive committee and audit committee. Burns is a citizen of the State of Florida.
- 15. Defendant Robert N. Burt ("Burt") has been a director of the Company since 2000. Burt has been a member of the board's audit committee and compensation committee. Burt is a citizen of the State of Illinois.
- 16. Defendant W. Don Cornwell ("Cornwell") has been a director of the Company since 1997. Cornwell has been chairman of the board's audit committee. Cornwell is a citizen of the State of New York.
- 17. Defendant William H. Gray, III ("Gray") has been a director of the Company since 2000. Gray has been a member of the board's corporate governance committee. Gray is a citizen of the State of Florida.
- 18. Defendant Constance J. Horner ("Horner") has been a director of the Company since 1993. Horner has been a chairman of the board's corporate governance committee and a member of the board's executive committee. Horner is a citizen of the Commonwealth of Virginia.
- 19. Defendant James M. Kilts ("Kilts") has been a director of the Company since 2007. Kilts has been a member of the board's compensation committee. Kilts is a citizen of the State of New York.

- 20. Defendant Jeffrey B. Kindler ("Kindler") has been the Company's chief executive officer ("CEO") since July 31, 2006. Previously, Kindler had been the Company's general counsel and chief compliance officer. Kindler has been a director of the Company since July 2006 and chairman of the board since December 2006. Kindler was a member of the board's executive committee. Kindler is a citizen of the State of Connecticut
- 21. Defendant George A. Lorch ("Lorch") has been a director of the Company since 2000. Lorch has been a member of the board's compensation committee. Lorch is a citizen of the State of Florida.
- 22. Defendant Suzanne Nora Johnson ("Nora Johnson") has been a director of the Company since 2007. Nora Johnson has been a member of the board's audit committee. Nora Johnson is a citizen of the State of California.
- 23. Defendant Dana G. Mead ("Mead") has been a director of the Company since 1998. Mead has been chairman of the board's compensation committee. Mead is a citizen of the Commonwealth of Massachusetts.
- 24. Defendant William C. Steere, Jr. ("Steere") has been a director of the Company since 1987. Steere has been chairman emeritus of the Company since July 2001, chairman of the board from 1992 to April 2001, and CEO from 1991 to 2000. Steere is a citizen of the State of Florida.
- 25. Defendant Stephen W. Sanger ("Sanger") has been a director of the Company since February 2009. Sanger is a citizen of the State of Minnesota.
- 26. Defendants Ausiello, Brown, Burns, Burt, Conwell, Gray, Horner, Kilts, Kindler, Lorch, Mead, Nora Johnson, Steere, and Sanger are all the fourteen members of the Company's board of directors.

- 27. Defendant Frank A. D'Amelio ("D'Amelio") has been the Company's chief financial officer ("CFO") since September 2007. D'Amelio is a citizen of the State of New Jersey.
- 28. Defendant Joseph M. Feczko ("Feczko") was the Company's chief medical officer from 2006 until 2009. Feczko is a citizen of the State of Connecticut.
- 29. Defendant Douglas M. Lankler ("Lankler") has been the Company's senior corporate counsel, senior vice president, and chief compliance officer. He signed the 2004 and 2009 Corporate Integrity Agreements. Lankler is a citizen of the State of New York.
- 30. Defendant Ian Read ("Read") has been the Company's senior vice president and president of its worldwide pharmaceutical operations. Read is a citizen of the State of Connecticut.
- 31. Defendants Henry A. McKinnell ("McKinnell"), a citizen of the State of Wyoming, was a senior executive and Company director from at least 1997 through February 2007.
- 32. Defendant David L. Shedlarz ("Schedlarz"), a citizen of the State of New York, was a senior executive and Company director at various times from 1995 to March 2005.
- 33. Defendant William R. Howell ("Howell"), a citizen of the State of Wyoming, was a Company director from June 2000 to April 2009. Howell was also a member of the board's audit committee from 2005 to at least 2008 and served as chairman of the audit committee from April 2005 to 2006.
- 34. Defendant Stanley O. Ikenberry ("Ikenberry"), a citizen of the State of Illinois, was the Company's lead independent director from October 2005 to February 2007 and a director from 1982 to March 2007. Ikenberry was also a member of the board's compensation

committee from 2005 to at least 2006 and a member of the board's corporate governance committee from at least 2003 to 2004.

- 35. Defendant Franklin D. Raines ("Raines"), a citizen of the District of Columbia, was a Company director from August 1993 to 1996 and again from October 1998 to April 2005. Raines was also a member of the board's compensation committee from at least 2003 to 2004.
- 36. Defendant Ruth J. Simmons ("Simmons"), a citizen of the State of Rhode Island and Providence Plantations, was a Company director from January 1997 to April 2007. Simmons was also a member of the board's corporate governance committee from at least 2003 to 2006 and was chairman of the board's corporate governance committee from at least 2004 to 2005.
- 37. Defendant Jean-Paul Vallès ("Vallès"), a citizen of the State of New York, was a Company director from 1980 to June 2005 and vice chairman of the board from March 1992 to October 1992. Vallés was also a member of the board's audit committee from at least 2003 to 2004.
- 38. Defendant Freda C. Lewis-Hall ("Lewis-Hall") was the Company's chief medical officer. She is a citizen of the State of New York.
- 39. Plaintiff has not made any demand on the Company's board of directors to institute this action against the individual defendants. To the extent that the demand requirement is governed by Delaware law, if a demand is made and rejected, the stockholder's challenge must be not to the underlying transaction, but to the board's decision not to bring the lawsuit. Delaware law thus substantially alters the nature of a derivative plaintiff's claim where demand has been made and conversely gives shareholders considering litigation good reason not to make demand.

- 40. Under Delaware law, pre-suit demand on the board is excused where the allegations of the complaint create a reasonable doubt that (1) a majority of the directors are disinterested and independent or (2) the challenged transaction was otherwise the product of a valid exercise of business judgment. In an "interested" director transaction, the business judgment rule is inapplicable to the board majority approving the transaction, and the inquiry ceases. In that event, futility of demand has been established by any objective standard.
- 41. Under Delaware law, if a corporate board has an even number of directors, demand is excused a futile if one-half of the board is interested. The Company's board has fourteen members.
- 42. Every member of the Pfizer board of directors was eligible to participate in the original 2004 stock plan and is eligible to participate in the amended and restated version of that plan, sometimes known as the Restated Plan. The board obtained stockholder approval of the 2004 plan by means of a proxy statement that omitted to disclose the facts concerning the government actions against the Company that were caused by the board itself. The board obtained stockholder approval of the 2009 Restated Plan by means of a proxy statement that omitted to disclose the facts concerning the government actions against the Company, including the \$2.3 billion that the Company paid to resolve these actions. As a result, every member of the Company's board is interested in the misconduct alleged in this complaint.
- 43. Even in the absence of a traditionally interested (or non-independent) board, demand is excused under the facts at bar.
- 44. The demand requirement and its exceptions are to encourage intra-corporate resolution of disputes and obtain the honest business judgment of the board on whether the litigation is in the best interest of the corporation and its shareholders. The business judgment

rule is inextricably bound to the demand rule. Where, however, a stockholder sues the board of directors over an act that is not a decision concerning the management of the business and affairs of the corporation, the business judgment rule does not apply. Delaware law excuses demand whenever the challenged act of the board is not the product of a valid exercise of business judgment, regardless of whether a majority of the board is disinterested and independent. The board's conduct concerning the misrepresentations and omissions in the proxy statements from 2002 through 2009, including the merger proxy statement by which the Company acquired Pharmacia Corporation, and in violating the express terms and provisions of the internal procedures for board supervision and regulation of members of the Company's management are not matters of business judgment, and they are not protected by the business judgment rule for the following reasons:

- (a) When, for the stockholders' annual meeting, a corporate board solicits stockholder's votes for directors and for compensation plans, the board owes the stockholders a statutory and fiduciary duty of full and fair disclosure, meaning that all material facts must be disclosed and no material facts may be omitted. This duty of disclosure is a thing apart from the duty and authority to deal with the business and property of the corporation. Courts give deference to a corporate board of directors as to questions of management of the corporation's business, but not as to questions of the board's performance of its disclosure duties, and for two reasons. First, a board's decision, even in good faith, to misstate or to omit a material fact cannot be defended on the grounds that reasonable persons could differ on the subject. Second, although courts may not be well suited to making business decisions, courts are well suited to deciding questions concerning the quality of, and circumstances surrounding, disclosures.
 - (b) As with Delaware law, under federal policy, there is no need for prior demand on

the board of directors with respect to the claim concerning misrepresentations and omissions in all the proxy statements from 2002 through 2009.

- (c) At bar all the proxy statements from 2002 through 2009 contain materially false or misleading statements and omissions concerning the conduct by the executive officers, and their supervision by the board and its committees.
- (d) The entire board is neither disinterested nor independent since every member of the board was required to distribute all the proxy statements from 2002 through 2009 without material misstatements and omissions.
- 45. The board's failure to prevent the repeated violations of federal statutes, rules, and regulations concerning the sale of medicines occurred in the face of repeated warnings from regulatory authorities and internal compliance officers. The misconduct occurred over a long time; it was not an isolated instance. As a result, (a) the board is conflicted because there is an extremely high risk of the directors' personal liability were they to institute this action; (b) the board members failed to perform duties that they knew were required, and they knew that such failure would cause serious injury to the Company; and (c) the failure of the board of directors to prevent the civil and criminal acts in this case was an egregious wrong in bad faith and in violation of law, and it cannot be the product of business judgment, i.e., directors are forbidden to cause a company to break the law in order to make a profit.
- 46. The repeated failure of the board and its committees to follow the requirements of its procedures and codes of conduct for supervising the officers and employees to prevent the well known recidivous white collar criminality is not protected by the business judgment rule. Accordingly, that failure excuses demand.

- 47. Pfizer and its subsidiaries are in the business of manufacturing and selling drugs, medicines, and other products for health care. It operates in the United States and worldwide. Pfizer's products have included many well known drugs, e.g., Bextra, Lipitor, Norvasc, Viagra, Zithromax, and Zoloft. Many of them generate revenues of more than \$1 billion per year.
- 48. The United States Food and Drug Administration ("FDA"), as the agency in charge of the Federal Food, Drug, and Cosmetic Act ("FDCA"), subjects Pfizer's business to extensive regulation and oversight. The FDCA requires Pfizer to establish the efficacy and safety of drugs before they can be sold.
- 49. The FDA approves drugs for specific uses and dosages. Any use of a drug that is inconsistent with or outside the scope of the FDA's approval is an off-label use.
- 50. The FDCA prevents Pfizer from promoting drugs for off-label use. Unless a product promoted for off-label use has adequate directions for the unapproved use, it is misbranded. A drug company that promotes a drug for off-label uses violates the FDCA proscription on misbranding by failing to provide adequate directions for the off-label use.
- 51. There are severe penalties, including criminal prosecution, injunctions, and seizure of misbranded or unapproved new drugs, for misbranding. Drug companies may also be subject to liability under the civil False Claims Act and the federal anti-kickback statute for misbranding. The False Claims Act also contains provisions that allow lawsuits on the government's behalf by private parties.
- 52. The individual defendants in office at the time created legal issues for the Company with Lipitor, a medication that reduces serum cholesterol.

- 53. In 2002, Pfizer paid \$49 million to settle charges that it had illegally given concealed discounts to a managed care organization in exchange for the organization's doctors to prescribe Lipitor to the organization's patients.
- 54. In addition, Pfizer agreed to enter into a five-year Corporate Integrity Agreement with the Department of Health and Human Services. That Agreement recited that Pfizer had begun compliance measures to train its personnel to comply with relevant law.
- 55. The Agreement also required Pfizer to maintain its compliance program and to designate a compliance officer to make at least semi-annual reports of compliance to the Company's board of directors.
- 56. That Agreement also required the Company to establish written compliance policies and procedures to meet federal health care program requirements. Specifically, those procedures were required to deal with the federal anti-kickback statute at 42 U.S.C. § 1320a-7b.
- 57. Nevertheless, despite the written compliance program the Company's board of directors allowed violations of federal law to continue.
- 58. The individual defendants in office at the time also created legal issues for Pfizer with Neurontin, an anticonvulsant medication. In 2004, the cost to the Company to settle these legal issues was \$430 million, of which \$240 million was in criminal fines and \$190 million was for civil claims.
- 59. The FDA approved the use of Neurontin for the management of pain caused by shingles in adults and for the control of epileptic seizures of adults if used in conjunction with another drug. The approved dosage was from 900 mg. to 1800 mg. per day. Neurontin is a drug with potentially dangerous side effects.

- Neurontin's use for epileptic seizures without another drug because of a failure to demonstrate efficacy. The FDA also rejected the use of Neurotin as a general pain medication and for the treatment of bipolar disorder, depression, migraine, and attention deficit disorder. The Company's management nevertheless promoted Neurotin for all the uses and at dosages that the FDA rejected, even through management did not know whether it was medically safe to do so.
- 61. In 2003 a former Company salesman, who was also a doctor and referred to as a medical liaison within the Company, filed a lawsuit alleging that a Company subsidiary had engaged in aggressive illegal sales and marketing practices with respect to Neurontin. The plaintiff there quoted a Company official to provide a snapshot of just how determined Company management was to break the law:

"Medical liaisons, this is Phil. I am calling in regard to the – you know, there's a Neurontin push that's supposed to be on. What we'd like to do is, anytime you're called out, just make sure that your main focus out of what you are doing is on Neurontin. ... When we get out there, we want to kick some ass on Neurontin, we want to sell Neurontin on pain. All right? And monotherapy and everything we can talk about, that's what we want to do."

- 62. The plaintiff there further explained that he was instructed to promote Neurontin regardless of whether it was medically appropriate. Moreover, he and his colleagues were instructed to make offers of paid consultancy engagements, offers of paid participation in studies, offers of junkets to first class resorts or hotels paid for by the Company, and offers of cash payments in order to persuade physicians to prescribe Neurontin for off-label uses, and to prescribe it at higher doses than approved by the FDA.
- 63. Next, the federal government opened an investigation. In 2004, a Company subsidiary pleaded guilty to criminal charges and accepted liability in response to civil charges

that it had fraudulently promoted the uses of Neurontin to treat a wide array of conditions for which the drug was not approved, in violation of the FDCA. The government observed that the sales campaign for Neurontin was replete with falsehood and misconduct. It found that the campaign used medical liaisons, who held themselves out as experts in particular diseases, to promote off-label uses for Neurontin, and that the Company paid physicians to allow sales representatives to see patients with the physicians. At such events the medical liaisons could offer advice regarding the patient's treatment which included recommendations, whether appropriate or not, of Neurontin.

- 64. To settle the charges, the Company's subsidiary pleaded guilty to felony violations of the FDCA. The Company had to pay a \$240 million criminal fine. This was a very large fine. It also cost the Company an additional \$190 million to resolve related civil claims, including Medicaid fraud.
- 65. In addition to the monetary costs, the Company signed another Corporate Integrity Agreement that required another corporate compliance program. This new Corporate Integrity Agreement once again recited that the Company had a compliance program in place.
- 66. This new Corporate Integrity Agreement required the Company to maintain a program to enable employees to report violations law and regulations, and required the maintenance of a record of each disclosure program received, the status of any review and any corrective action taken in response. This disclosure program was required to be non-retaliatory and to allow for anonymous communications with confidentiality.
- 67. This new Corporate Identity Agreement placed special emphasis on the duties of the directors to monitor and oversee management to prevent future illegal marketing and sales promotions of its drugs. The new agreement once again required the Company's chief and

deputy compliance officers to make at least semi-annual reports concerning compliance matters directly to the Company's board of directors. Finally, the new Agreement required the directors to adopt and abide by a written code of conduct.

- 68. This code of conduct would, among other things, require that all Company officers and employees comply with all federal health care program requirements and all FDA requirements and that all officers directly involved certify in writing that they read, understood and would follow the code of conduct, and that they would comply with all federal health care program requirements and FDA requirements.
- 69. The new Agreement also required detailed, written policies and procedures regarding the operation of the compliance program. They would address (a) the methods for selling, marketing, promoting, advertising, and disseminating information about off-label uses of the Company's products in compliance with all FDA requirements; (b) policies designed to assure that speaker meetings, advisory board meetings and all other consulting arrangements would be used for legal purposes in accordance with applicable federal health care program requirements and with FDA requirements relating to the off-label uses of products; (c) policies designed to assure that Company's sponsorship or funding of grants, research or related activities comply with all applicable federal health care program and FDA requirements; and (d) the methods for selling, marketing, and promoting Company's products in compliance with all applicable federal health care program requirements, including, but not limited to, the federal anti-kickback statute.
- 70. As hereinafter alleged, it did not work. The Company's board of directors allowed violations of federal law to continue unabated, despite the new Corporate Integrity Agreement.

- 71. The Company's drug, Genotropin is an anabolic steroid that was approved by the FDA for the limited use of treating children who suffer from growth failure because it can pose substantial risks to human health. The Company's management caused violations that required the Company to pay criminal fines of \$34.6 million because of Genotropin. The medical literature has reported that anabolic steroids can present dangerous, irreversible side effect, such as stunting of height in males and voice and body and facial hair changes in females.
- 72. The FDCA has also recognized the substantial health risks posed by the use of anabolic steroids such as Genotropin for off-label applications. This statute provides serious criminal sanctions for any unauthorized use of anabolic steroids, especially if the offense involves a minor.
- 73. The FDA has not approved the use of Genotropin for athletic performance enhancement, anti-aging, or cosmetic use. The Company's management has not submitted information to the FDA asserting that such other uses would be safe. Knowing that it was illegal to do so, and with the intent to defraud and mislead, the Company's management marketed Genotropin for unapproved uses, including athletic performance enhancement, anti-aging, and cosmetic use.
- 74. In or about March 2007, a Company subsidiary pleaded guilty for the illegal promotion and sales practices for Genotropin and admitted that during visits to anti-aging doctors and clinics, it knowingly made misleading representations about the effectiveness of Genotropin as an anti-aging medication. It had reported millions of dollars in gross revenue from selling Genotropin for various unapproved uses. The Company's subsidiary admitted that some of the individuals who took Genotropin did so without medical reason, but only to obtain better skin tone, better skin elasticity, better general appearance, and better strength.

- 75. In or about March 2007, a Company subsidiary also pleaded guilty to an intentional violation of the federal anti-kickback statute in connection with Genotropin.
- 76. These guilty pleas concerning Genotropin required the Company to pay \$34.6 million in criminal fines.
- 77. Still, the Company's board of directors again decided to take no action to prevent repetition of management's criminal conduct. Instead, the Company's board of directors knowingly encouraged or consciously disregarded that behavior.
- 78. Despite these repeated sanctions, the Company's board allowed the same illegal conduct to continue. As a result, Pfizer suffered the largest government fines in history.
- 79. On September 2, 2009, Pfizer officially announced its agreement to pay a criminal fine of \$1.195 billion and to forfeit \$105 million to settle criminal charges related to the illegal, off-label marketing and promotion of Bextra, a non-steroidal anti-inflammatory drug and competitor of Vioxx, manufactured and sold by another company. This was the biggest criminal fine that a United Sttes court had ever imposed.
- 80. Pfizer further agreed to pay an additional \$1 billion to resolve allegations under the civil False Claims Act that between January 2001 and October 31, 2008, Pfizer engaged in the illegal promotion and sales practices of Aricept, Celebrex, Geodon, Lipitor, Lyrica, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zyrtec, and Zyvox.
- 81. Between January 2001 and October 31, 2008, the Board received many warnings from the FDA and Company personnel that Pfizer employees were violating FDA regulations, Federal healthcare program regulations or the Federal anti-kickback statute with regard to a number of these drugs. But, the Company's board always consciously ignored those warnings. Instead, Company's management retaliated against some of the employees who had made the

reports of illegal behavior. This permitted and encouraged the lawbreaking employees to continue their illegal behavior, thereby placing the Company and its shareholders at risk.

- 82. In or about January 2001, Pharmacia Corporation, a Delaware corporation (then not owned by Pfizer), sought FDA approval for the sale of Bextra, a drug that inhibits an enzyme that transmits inflammation and pain. Pharmacia specifically requested that the FDA approve use of Bextra for the treatment of acute pain and dysmenorrhea by administering 40 mg. of Bextra per day and, in addition, for the treatment of chronic symptoms of arthritis at a dose of 10 mg. of Bextra per day, stating that some patients could benefit from an additional 10 mg. per day.
- 83. But the FDA denied Pharmacia's request, and rejected approval for Bextra to be used to treat acute pain, on safety concerns identified in a study of Bextra showing an increase of serious risks, including death.
- 84. Because of a concern that Bextra could cause patients to develop blood clots, the FDA only approved Bextra for osteoarthritis and rheumatoid arthritis at a dose of 10 mg. per day, and dysmenorrhea at a dose of 20 mg. per day.
- 85. The FDA informed Pharmacia of its findings and recommendations and the reasons therefor. Pharmacia therefore knew that the off-label prescription of Bextra for higher dosages than 20 mg per day, or for other uses than the FDA had approved, would be dangerous to human health and life.
- 86. Despite the FDA's warnings, Pharmacia immediately started to draw up plans to market Bextra to a broad range of patients, and for purposes that the FDA had expressly forbidden.
- 87. In or about 2002, Pharmacia made an agreement with Pfizer to market Bextra together with Pfizer's similar drug known as Celebrex. Pfizer acquired Pharmacia in a merger

on April 16, 2003. As part of the marketing alliance, before the merger, Pfizer and Pharmacia shared information about sale and promotion strategies for both Bextra and Celebrex. The merger proxy statement omitted to disclose the FDA's warnings about Bextra, and the two companies' illegal plans.

- 88. In 2003, after Pfizer acquired Pharmacia, they continued to promote Bextra for dangerous off-label uses. They held many consultant meetings to promote unapproved uses and dosages of Bextra, and paid physicians to further spread its message about unapproved uses and dosages of Bextra.
- Moreover, they subsidiary also: (a) illegally promoted Bextra with false and misleading safety and comparative claims; (b) created sham doctor requests for medical information about unapproved uses in order to send unsolicited information about unapproved uses and dosages of Bextra; (c) distributed promotional samples with unapproved dosages to surgeons and other doctors who had no FDA-approved use for those samples; (d) funded purportedly independent continuing medical education programs to promote Bextra for unapproved uses, including acute pain and surgical pain; and (e) employed a publication strategy by funding, sponsoring and sometimes drafting articles about Bextra for unapproved uses and dosages in order to promote such unapproved uses and dosages.
- 90. In or about September 2004, the Company learned of wide-spread reports that drugs similar to Bextra had been withdrawn from the market because of safety concerns, such as heart attack and stroke. In October 2004, Pfizer also learned the results of another study of Bextra that showed a statistically significant increase in thrombembolic cardiovascular events in patients taking Bextra. Pfizer management nevertheless continued its illegal practice of

promoting Bextra off-label for uses and dosages other than the uses and dosages approved by the FDA.

- 91. In January and February 2005, Pfizer received warnings from the FDA and from European regulators concerning Pfizer's claims about the safety of Bextra. Under the 2004 Corporate Integrity Agreement, the compliance officers were obligated to inform the Pfizer board of these warnings. Despite the warnings, Pfizer continued its illegal practice of promoting Bextra off-label for uses and dosages that were not approved by the FDA.
- 92. On January 18, 2005, the European regulators held a hearing with Pfizer and other pharmaceutical companies about the safety of the Bextra class of drugs. The outcome of the European review would adversely affect Pfizer's ability to sell Celebrex and Bextra in Europe and was of exceptional importance to Pfizer. Upon information and belief because of the financial importance to Pfizer, the Pfizer board was informed of this hearing and the safety concerns underlying the European review.
- 93. On or about April 7, 2005, the FDA requested that Pfizer voluntarily withdraw Bextra from the U.S. market. Because of Bextra's association with an increased risk of serious adverse events Pfizer agreed to do so, and ceased all sales and promotion activities in the U.S., including the illegal promotion of off-label use for Bextra.
- 94. In or about August 2009, Pfizer's subsidiary Pharmacia agreed to plead guilty to a criminal felony charge of violating the FDCA, admitting that it intentionally, and with the intent to deceive and defraud, marketed Bextra for uses and dosages that were not approved by the FDA. The deceptive sales conduct regarding Bextra took place from February 2002 through April 2005. During this time, Pfizer knew that Bextra was dangerous to human life.

- 95. The amount of the fine reflected the seriousness and scope of Pfizer's crimes and that they had continued over an extensive time period. The fine demonstrated that such blatant and continued disregard of the law will not be tolerated.
- 96. To settle the criminal charges concerning Bextra, Pfizer paid \$1.3 billion consisting of \$1.195 billion in fines and \$105 million in forfeitures. In addition Pfizer paid \$1 billion to settle allegations that it had violated the federal civil false claims act, including prohibited off-label use and dosage promotions, and violations of the federal anti-kickback statute, with respect to 13 different drugs. This payment involved Company-wide marketing practices and some of Pfizer's most material and important products. These violations are not isolated incidents, or the work of a small number of employees. The payments to settle those charges was the culmination of a deliberate general business strategy to promote illegal off-label use, including by making false or unsubstantiated claims regarding the efficacy and safety of Pfizer drugs and payment of illegal remuneration to doctors to induce them to prescribe Pfizer drugs.
- 97. The illegal sales and promotion practices covered by the 2009 settlement spanned more than 7 and a half years and 13 different drugs. During this time, the Company's directors received repeated reports that Pfizer employees were engaged in illegal sales and promotion practices, including promotion of off-label uses and dosages, the dissemination of false and misleading information to induce doctors to prescribe Pfizer drugs, and offers of remuneration to doctors who did prescribe Pfizer drugs. The directors also knew that, if true, such alleged practices put at risk the health and lives of patients.
- 98. Kindler was general counsel for Pfizer from 2002 through 2006 and was the Company's chief compliance officer. He was specifically charged under the Corporate Integrity

Agreements as the individual at the Company responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the federal health care laws, FDA regulation and the Corporate Integrity Agreements and for monitoring the day-to-day compliance activities engaged in by Pfizer management as well as for any reporting obligations created under the Corporate Integrity Agreements.

- 99. The 2002 and 2004 Corporate Integrity Agreements emphasized the important monitoring and oversight role of the directors in ensuring that Pfizer management would not engage in illegal marketing and sales promotions of its drugs. They were aided in this by semi-annual compliance reports. In addition, the compliance officers were required to inform the directors about reports from employees under the disclosure program that Pfizer employees were violating federal law, as well as FDA notice of violation letters warning of the very same misconduct violating federal law that were part of the \$2.3 billion settlement.
- 100. During the relevant period, Pfizer's chief and deputy compliance officers repeatedly informed the Pfizer board of allegations that Pfizer employees were engaged in illegal sales and promotion practices. Among other red flags, the board was informed of violations regarding Geodon, Lipitor, Viagra, Zyrtec, Zithnomax, Zoloft, Norvasc, and Glucotrol. The board received repeated warnings concerning Bextra and Clebrex. The board learned of multiple settlements of enforcement actions for millions of dollars.
- 101. Many of the red flags reported to the Pfizer board involve similar illegal conduct by different Pfizer employees. This raised an additional warning as to whether the illegal sales and marketing practices were condoned if not encouraged by senior management.
- 102. The directors knew that, if true, the warnings put at risk the viability of Pfizer's business, and that they had a duty to investigate and stop those practices from continuing. Each

of them had undertaken a duty to oversee the company's compliance with federal law and regulations through the Company's director code of conduct. This was especially true of the directors who were members of the corporate governance and audit committees, because those were expressly created to monitor the Company's business and compliance process. The charter of the audit committee provides that members of the committee must monitor the Company's compliance with laws, regulations, and internal procedures, including compliance with healthcare program regulations, FDA requirements and the 2004 Corporate Integrity Agreement. The charter of the corporate governance committee provides that members of the committee must stay informed regarding matters of Pfizer's corporate governance and to monitor emerging issues potentially affecting the reputation of the pharmaceutical industry and the Company.

- in the very large criminal and civil fines, chose not to properly investigate and end the illegal sales and promotion practices that were taking place. In the meantime, Company management retaliated against a number of the employees who had made the reports of illegal behavior. The directors' deliberate inaction and management's retaliation against employees who reported illegal sales and promotion practices despite the obligation in the 2004 Corporate Integrity Agreement that the disclosure program include a nonretaliation policy encouraged lawbreaking employees to continue their illegal behavior. The directors' and officers' deliberate inaction also created a culture of tolerating, if not rewarding and encouraging, unlawful conduct. The directors' and officers' conscious breach of duty thereby placed the Company and its shareholders at risk.
- 104. The board's decision to allow a large part of Pfizer's business to be run as a white collar criminal enterprise has put (and if not stopped will continue to put) Pfizer and its

shareholders at risk. If Pfizer were again convicted of a crime, it would result in ruinous consequences for Medicaid and Medicare patients who would have to either somehow pay out-of-pocket pocket for vital medicines the Company produces or go without. As many millions of patients would not be able to afford Pfizer products, further convictions would therefore also lead to catastrophic results for Pfizer and its shareholders.

- 105. Pfizer's proxy statements for the years of 2002-2009 contained materially false or misleading statements and omissions because they failed to disclose that the rampant criminality that pervaded the Company's management marketing methods, which the directors were required to prevent, but did not. The directors' malfeasance, misfeasance, and nonfeasance exposed the Company and its shareholders to tremendous regulatory, reputational and financial risk. The board's misconduct violated the directors' own criteria for board membership, and caused Pfizer's shareholders to elect them year after year.
- 106. All the proxy statements omitted the crucial fact that after receiving reports of management's widespread violations of federal law, the board chose not to stop this ongoing illegal activity. Rather, the board chose to approve of this conduct as part of Pfizer's business plan, or at the very least consciously chose to disregard this information in intentional dereliction of its fiduciary duties of overseeing Pfizer's compliance with federal law.
- 107. This omitted information was particularly material to Pfizer shareholders because it would have demonstrated that Pfizer's incumbent directors did not meet Pfizer's stated criteria for board membership.
- 108. In addition, the 2002 merger proxy statement in which the Pfizer board solicited Company stockholders to vote for the issuance of Pfizer shares plus cash in lieu of fractional

shares to acquire Pharmacia, omitted to disclose the reckless plan between the two merger participants to engage in illegal off-label marketing of Bextra.

- 109. In all the following proxy statements that were distributed for annual meetings the Pfizer board solicited stockholders' proxies for re-election to the board, but the proxy statements omitted to disclose the illegal off-label marketing plans of the Company and the regulatory and criminal sanctions that the Company had suffered.
- board solicited the stockholders' proxies to vote for a stock plan in which every director was eligible to participate. But those two proxy statements omitted to disclose the unfaithful and torpid misconduct of the board in failing to prevent the illegal marketing methods of Company management and that the board beneficiaries of the stock plans had allowed these illegal marketing methods to continue. Neither the 2004 nor the 2009 proxy statements had disclosed the criminal and civil sanctions that the Company had sustained because of that illegal conduct. By the time the directors distributed the 2009 proxy statement, the Company had already booked the \$2.3 billion charge in the fourth quarter of 2008.

FIRST CLAIM FOR RELIEF

(On Behalf of the Company Against All Other Defendants)

111. Paragraphs 1 through 110 state a stockholder's derivative claim on behalf of the Company for breach of fiduciary duty of loyalty and commission of waste under Delaware law because of violations of federal and state laws concerning the marketing and promotion of drugs.

SECOND CLAIM FOR RELIEF

(On Behalf of the Company Against All Directors Who Solicited Proxies and All Other Defendants Who Permitted Their Names To Appear In Proxy Statements)

112. Paragraphs 1 through 110 state a stockholders' derivative claim on behalf of the Company under federal law for violations of 15 U.S.C. 78n(a) and 17 C.F.R. § 240.14a-9.

THIRD CLAIM FOR RELIEF

(Against All Directors And Former Directors Who Solicited Proxy Statements)

113. Paragraphs 1 through 110 state a stockholder's derivative claim on behalf of the Company under Delaware law for breach of the duty of loyalty in failing to make correct disclosures in proxy statements.

WHEREFORE, plaintiff prays for the following relief:

- A. An equitable accounting, including disgorgement, in favor of the Company for the losses that it has and will sustain by virtue of the conduct alleged herein;
 - B. An injunction against participation in the stock plan by the directors;
- C. A mandatory injunction requiring correction of the false statements in the 2002 through 2009 proxy statements;
 - C. A mandatory injunction requiring stockholder reapproval of the stock plans;
- E. Awarding plaintiff the costs and disbursements of this action, including reasonable accountants, experts, and attorneys' fees; and
- F. Granting such other, further relief, whether similar or different, including monetary recovery, as by this Court may be deemed just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: New York, New York October 2, 2009

> Alexander Arnold Gershon (AG 3809) Regina M. Calcaterra (RC 8583)

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DOCKET NUMBER 09-cv-7822

NOTE: Please submit at the time of filing an explanation of why cases are deemed related.

JS 44C/SDNY

DEMAND \$

Check YES only if demanded in complaint JURY DEMAND: YES NO

OTHER

CIVIL COVER SHEET REV. 1/2008 The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local subsection. This form, approved by the undicial Conference of the United States in September 1974, is required for use of the Clerk of Court for the purpose of the Court for the Court **PLAINTIFFS DEFENDANTS** The Port Authority of Allegheny County Retirement and Disability Allowance Plan for Employees Represented by Local 85 of the Amalgamated Transit Dennis A. Ausiello, et. al. ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER) ATTORNEYS (IF KNOWN) Barrack, Rodos & Bacine 1350 Broadway, Suite 1001 Alexander Arnold Gershon New York, New York 10018 (2)2) 688 - 0782 Gloria Kui Melwani CACHIERS CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE) (DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY) 15 U.S.C. 78n(a) for false or misleading proxy statement and breach of fiduciary duty Has this or a similar case been previously filed in SDNY at any time? No? Ves? Judge Previously Assigned Hon. Rakoff If yes, was this case Vol. ☐ Invol. ☐ Dismissed. No ☑ Yes ☐ If yes, give date & Case No. (PLACE AN [x] IN ONE BOX ONLY) NATURE OF SUIT TORTS **ACTIONS UNDER STATUTES** CONTRACT PERSONAL INJURY PERSONAL INJURY FORFEITURE/PENALTY BANKRUPTCY OTHER STATUTES I 1110 INSURANCE 310 AIRPLANE [] 362 PERSONAL INJURY -MED MALPRACTICE MARINE AGRICUI TURE []610 []422 APPEAL [] 315 AIRPLANE PRODUCT []400 STATE i i 130 MILLER ACT OTHER FOOD & 1 1620 LIABILITY 28 USC 158 REAPPORTIONMENT []365 [] 140 PERSONAL INJURY NEGOTIABLE DRUG []423 WITHDRAWAL [] 320 ASSAULT, LIBEL & []410 ANTITRUST INSTRUMENT RECOVERY OF PRODUCT LIABILITY []625 DRUG RELATED 28 USC 157 []368 1430 BANKS & BANKING SLANDER ASBESTOS PERSONAL **X**) 150 SEIZURE OF [] 330 FEDERAL EMPLOYERS 1450 COMMERCE 1460 DEPORTATION INJURY PRODUCT OVERPAYMENT & ENFORCEMENT PROPERTY LIABILITY 21 USC 881 PROPERTY RIGHTS [] 470 RACKETEER INFLU-ENCED & CORRUPT LIABILITY OF JUDGMENT MEDICARE ACT LIQUOR LAWS [] 340 MARINE []151 []152 PERSONAL PROPERTY 1 1640 RR & TRUCK 1 1820 COPYRIGHTS [] 345 MARINE PRODUCT ORGANIZATION ACT RECOVERY OF j 650 AIRLINE REGS 830 PATENT LIABILITY (RICO) OTHER FRAUD DEFAULTED STUDENT LOANS []660 OCCUPATIONAL MOTOR VEHICLE []840 TRADEMARK CONSUMER CREDIT TRUTH IN LENDING OTHER PERSONAL [] 355 MOTOR VEHICLE PRODUCT LIABILITY SAFETY/HEALTH i 490 CABLE/SATELLITE TV SELECTIVE SERVICE (EXCL VETERANS) RECOVERY OF [] 380 []690 OTHER PROPERTY DAMAGE []153 SOCIAL SECURITY []360 [] 850 OTHER PERSONAL SECURITIES/ []385 OVERPAYMENT OF VETERAN'S PROPERTY DAMAGE COMMODITIES/ INJURY PRODUCT LIABILITY LABOR [] 861 HIA (1395ff) EXCHANGE BENEFITS 862 BLACK LUNG (923) f 1160 **STOCKHOLDERS** FAIR LABOR STANDARDS ACT []710] 863 DIWC/DIWW (405(g)) CHALLENGE SUITS SSID TITLE XVI 12 USC 3410 OTHER LABOR/MGMT f 1190 []720 [] 865 RSI (405(g)) [] 890 OTHER STATUTORY CONTRACT RELATIONS **ACTIONS** I 1195 []730 CONTRACT LABOR/MGMT AGRICULTURAL ACTS PRODUCT REPORTING & **FEDERAL TAX SUITS ACTIONS UNDER STATUTES** 1 892 ECONOMIC LIABILITY DISCLOSURE ACT STABILIZATION ACT 1 196 FRANCHISE []740 []790 RAILWAY LABOR ACT [] 870 TAXES (U.S. Plaintiff or OTHER LABOR **CIVIL RIGHTS** [] 893 ENVIRONMENTAL PRISONER PETITIONS Defendant) MATTERS LITIGATION [] 871 IRS-THIRD PARTY] 441 VOTING []894 ENERGY [] 510 MOTIONS TO []791 EMPL RET INC 26 USC 7609 ALLOCATION ACT REAL PROPERTY [] 442 EMPLOYMENT VACATE SENTENCE SECURITY ACT []895 FREEDOM OF INFORMATION ACT []900 APPEAL OF FEE []443 HOUSING/ 28 USC 2255 HABEAS CORPUS ACCOMMODATIONS [] 210 LAND IMMIGRATION WELFARE 1535 DEATH PENALTY CONDEMNATION DETERMINATION UNDER EQUAL []445 AMERICANS WITH DISABILITIES -1540 MANDAMUS & OTHER []462 1220 FORECLOSURE NATURALIZATION [] 230 CIVIL RIGHTS APPLICATION HABEAS CORPUS-RENT LEASE & ACCESS TO JUSTICE EMPLOYMENT [] 555 PRISON CONDITION EJECTMENT []463 []446 AMERICANS WITH [] 240 TORTS TO LAND ALIEN DETAINEE DISABILITIES -OTHER OF STATE STATUTES []245 TORT PRODUCT []465 OTHER IMMIGRATION [] 440 OTHER CIVIL RIGHTS LIABILITY []290 ALL OTHER REAL PROPERTY Check if demanded in complaint: CHECK IF THIS IS A CLASS ACTION DO YOU CLAIM THIS CASE IS RELATED TO A CIVIL CASE NOW PENDING IN S.D.N.Y.? UNDER F.R.C.P. 23 IF SO, STATE:

JUDGE Hon. Rakoff

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DEFENDANTS

Dennis A. Ausiello Michael S. Brown M. Anthony Burns Robert N. Burt W. Don Cornwell Frank A. D'Amelio William H. Gray III Constance J. Horner James M. Kilts Jeffrey B. Kindler George A. Lorch Dana G. Mead Suzanne Nora Johnson Stephen W. Sanger William C. Steere, Jr. Pfizer Inc.

The above defendants are at 235 East 42nd Street, New York, New York 10017

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Freda C. Lewis-Hall - 281 SAYRE DR, PRINCETON, NJ 08540-5858

EXPLANATION OF WHY CASES ARE RELATED

This action alleges that the Board of Directors and/or Pfizer Inc. and other named defendants are liable for violations of the federal securities laws, breaches of fiduciary duty and other causes in connection with their conduct in causing or failing to prevent misconduct that has harmed Pfizer Inc. The complaint arises from similar conduct by many of the same defendants, and will involve many of the same exhibits and witnesses, as those in *Klein v. Ausiello*, 09-cv-7822, which is currently pending before the Honorable Jed S. Rakoff.